

Patient's Guide
Transcatheter Closure of a Patent Foramen Ovale Using the
AMPLATZER® PFO Occluder System

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This Guide is not intended as a substitute for consulting with your doctor. You should talk to your doctor about any questions or concerns you have about the diagnosis or treatment of your medical condition.

Humanitarian Use Device - Authorized by Federal law for the non-surgical closure of a *patent foramen ovale* (PFO) in patients with recurrent *cryptogenic stroke* due to presumed *paradoxical embolism* through a patent foramen ovale and who have failed *conventional drug therapy*. The effectiveness of this device for use in this indication has not yet been demonstrated.

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GLOSSARY OF TERMS

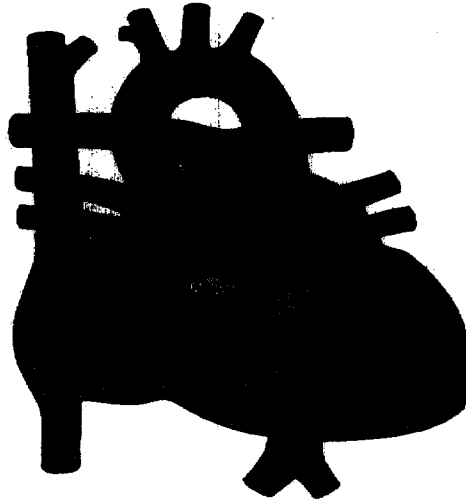


Figure 1
Diagram of a Normal Heart

Angiogram – An x-ray of blood vessels or heart chambers filled with contrast media that allows your doctor to see moving pictures of your heart.

Antiplatelet and/or Anticoagulation Therapy – Medication that helps prevent blood clots.

Apnea – Absence of breathing.

Arrhythmia – Loss of regular heart rhythm.

Atrial Septum – The wall that divides the left and right atria.

Atrium – *pl. atria* One of the upper two chambers of the normal heart (right and left atrium).

Brachial plexus injury – injury to the nerves in the arm and lower neck that can result from positioning a patient on an x-ray table.

Cardiac catheterization – A procedure in which *catheters* are passed through the arteries and veins of the heart. Pressures are measured, and blood samples are taken from within the heart and its major blood vessels.

Catheter – a sterile, flexible, hollow tube designed for insertion into a vessel to permit injection or withdrawal of fluids or to pass devices through.

Carotid Arteries – Two major arteries, one on each side of the neck, that carry blood to the head.

Conventional Drug Therapy - A therapeutic dosage of *anticoagulation* medication.

Cryptogenic Stroke: A *stroke* occurring where the origin is unknown.

Echocardiography/Echocardiogram (Echo) – The use of ultrasound to look at the heart, valves and great vessels.

Endocarditis – Redness, and swelling of the lining of the heart and its valves.

Endocarditis Prophylaxis – Medicine taken to minimize risk of *endocarditis*.

Embolus – *pl. emboli*, A mass, such as an air bubble or blood clot, that travels in the bloodstream and gets stuck in a small blood vessel and blocks or decreases blood flow.

Esophagus – The part of the body that connects the mouth to the stomach.

Hematoma – A mass of blood which is a result of a break in a blood vessel.

Hypertension – High blood pressure.

Hypotension – Abnormally low blood pressure.

Imaging Probe – A flexible, tube-like medical instrument with a camera that shows a picture on a screen of what is inside the body.

Magnetic Resonance Imaging (MRI) – A type of test used to visualize body tissue that uses a magnetic field.

Paradoxical Embolism – When a small clot or piece of debris from the venous system passes through a *patent foramen ovale* into the arterial side of the heart creating decreased or blocked blood flow in an artery.

Patent Foramen Ovale (PFO) – a term used to describe a small hole in the section of the *atrial septum* that is called the Foramen Ovale.

Stroke – The sudden loss of brain function caused by a blocked or broken blood vessel to the brain.

Thrombus – Blood clot.

Transient Ischemic Attack (TIA) – A temporary lack of oxygen to the brain.

Transesophageal Echocardiography (TEE) – An ultrasound test to visualize the heart and defect, where an *imaging probe* with a camera is placed in the *esophagus*.

Transcatheter – Through a *catheter*.

Valvular Regurgitation – An abnormal backward flow of blood through a valve.

Ventricles (right and left) – One of the two lower chambers of the heart.

INTRODUCTION

You have been diagnosed as having a patent foramen ovale. The foramen ovale is an opening in the atrial septum that allows blood to flow between the atria in the fetus prior to birth. Normally the foramen ovale closes at or shortly after birth. If the foramen ovale does not close it is referred to as a *patent foramen ovale (PFO)*. A PFO may allow blood or emboli to cross from the right atrium to the left atrium. This is called a right to left shunt.

If an emboli crosses from the right atrium to the left atrium this is called a *paradoxical embolism*. Paradoxical embolism can result in a stroke if the emboli blocks an artery to the brain. Stroke due to paradoxical embolism can recur in patients who are taking appropriate doses of anticoagulation medications (blood thinners).

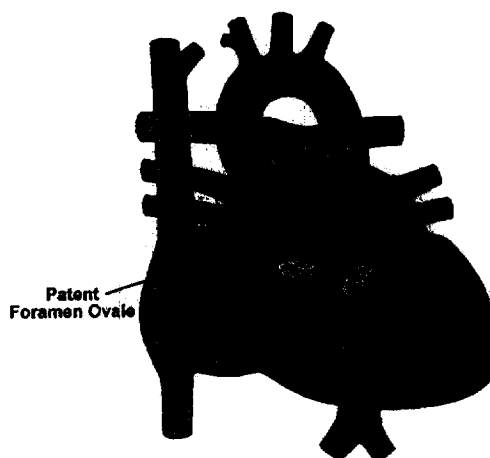


Figure 2
Heart with Foramen Ovale

Your physician has recommended that your PFO defect be closed using an implantable AMPLATZER PFO Occluder device. Placement of the AMPLATZER PFO Occluder involves standard interventional *cardiac catheterization* techniques. The AMPLATZER PFO Occluder is placed in your heart using a *catheter*.

PURPOSE OF THE DEVICE (INDICATIONS FOR USE)

The AMPLATZER PFO Occluder is a *percutaneous, transcatheter, occlusion* device intended for the non-surgical closure of *patent foramen ovale (PFO)* in those patients who have had recurrent *cryptogenic strokes* despite being on medication to prevent strokes. The effectiveness of this device has not been demonstrated for this indication.

DESCRIPTION OF THE DEVICE

The AMPLATZER PFO Occluder is a wire mesh made out of nickel and titanium (Nitinol). The wire mesh is filled with polyester fabric to help close the defect. The polyester fabric is securely sewn into the device with a polyester thread.

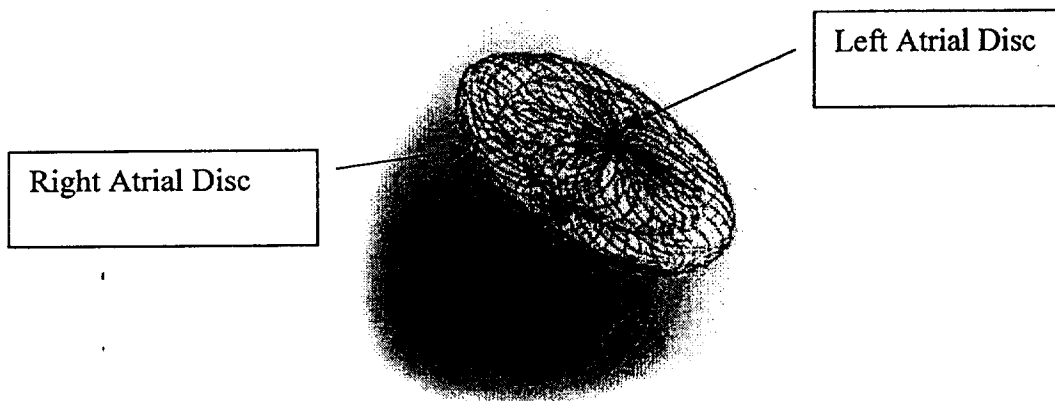


Figure 3
AMPLATZER PFO Occluder

The AMPLATZER PFO Occluder has a specially designed delivery system that your doctor will use to attach, deliver and release the AMPLATZER PFO Occluder in your heart.

WHEN THE DEVICE SHOULD NOT BE USED (CONTRAINDICATIONS)

If you have any of the following conditions, you may not be a good candidate to receive the device.

- If you have disease in one or more of the arteries to the brain.
- If you have blood clots in your heart.
- If you have a bleeding disorder, untreated ulcer or if you are unable to take aspirin. Your doctor may be able to prescribe another blood thinner, however sometimes that is not possible.
- If you, your heart or your veins are very small or if you cannot undergo the procedure, you may not be able to receive the device.
- If you have an infection anywhere in your body. You may receive the device only after the infection is gone.
- If your heart does not have enough tissue to secure the device.
- If your blood clots easily.

POTENTIAL RISKS AND BENEFITS

What are the risks?

There are risks with *cardiac catheterization* procedures as well as additional risks that may be associated with the device. Potential risks include, but are not limited to:

- Allergic dye reaction
- Anesthesia reactions
- Temporary absence of breathing (*Apnea*)
- Loss of regular heart rhythm (*Arrhythmia*)
- Bleeding around introducer sheaths
- Injury to the nerves in the arm and lower neck (*Brachial plexus injury*)
- Bruising at the groin or arm
- Changes in blood pressure
- Death (related to device or procedure)
- Dislodgment of the device
- An air bubble or clot that blocks blood flow in a vessel (*Embolus*)
- Redness and swelling of the lining of the heart (*Endocarditis*)
- Fever
- Headache/migraine
- A mass of blood from a broken blood vessel (*Hematoma*)
- Too high or too low blood pressure (*Hypertension; hypotension*)
- Incomplete sealing of the defect
- Infection
- Injury to the artery, vein or nerves in the groin or neck
- Perforation of *esophagus* (from the TEE camera), vein or heart
- *Stroke* or *transient ischemic attacks (TIA)*
- Blood clots (*Thrombus*)
- Abnormal backward flow of blood through a valve (*Valvular Regurgitation*)
- X-ray exposure is increased

If the device were to be dislodged, you may need surgery for its removal. Your PFO would be repaired at the same time. Surgery following device placement may be more difficult. No deaths have been encountered because of device failure. Because the AMPLATZER PFO Occluder device is new, there may be other risks that are not known at this time.

What are the benefits of this procedure?

The benefits of having a device are:

1. Surgery to close your PFO is avoided. This results in:
 - Shorter hospital stay and recovery time
 - No chest scar
2. You may not need to be on life long drug therapy to prevent *strokes*.

WHAT SHOULD I EXPECT DURING AND AFTER THE PROCEDURE?

What to expect before, during, and after the procedure will vary. Read this information carefully and discuss any questions or concerns you have with your doctor.

1. Your procedure will be performed in the heart catheterization laboratory, or “cath lab.” You will lie on an x-ray table, and an x-ray camera will move over your chest during the procedure. The staff will monitor your heart by attaching several small sticky patches to your chest.
2. Your doctor will give you an anesthetic. It may be general or local. This will depend on the technique the doctor uses to place the device. There should not be significant discomfort.
3. Your doctor may place an *imaging probe* in your mouth and move it down into your *esophagus*. This imaging probe makes it possible for the doctor to see your heart up close with an *echocardiography* machine.
4. Your doctor will insert a *catheter* through a vein, and then navigate it through some of your body’s largest veins until it reaches your heart. The doctor will perform a procedure (*angiogram*) to visualize your heart and the PFO.

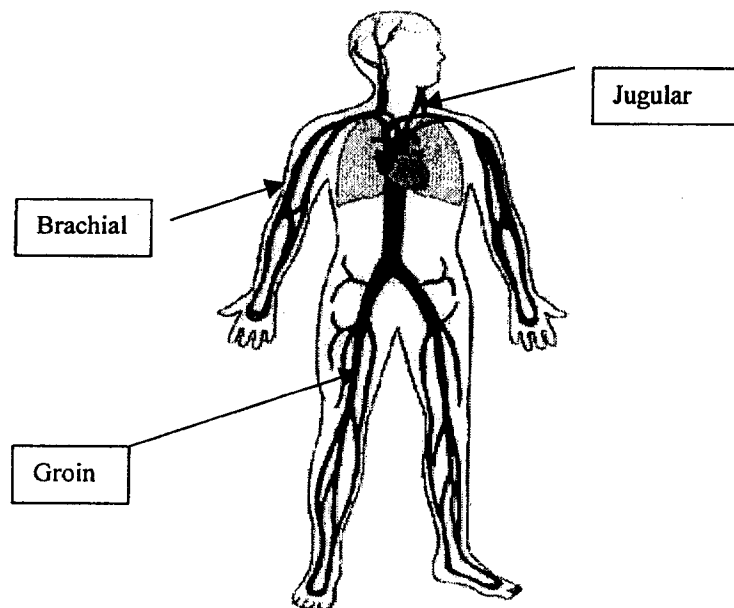


Figure 4
Vein Access Sites

5. Your doctor will then measure the pressure and oxygen content in different chambers of your heart.
6. The appropriate size device is screwed onto a cable, put into a special *catheter* and advanced through your PFO. Your doctor will then push the device out of the catheter until the discs of the device sit on each side of the PFO.
7. Your doctor carefully studies the device's position in your heart. When your doctor is satisfied with the device position, the device is released by unscrewing the cable that was used to slide it through the catheter. The AMPLATZER PFO Occluder is now implanted in your heart.

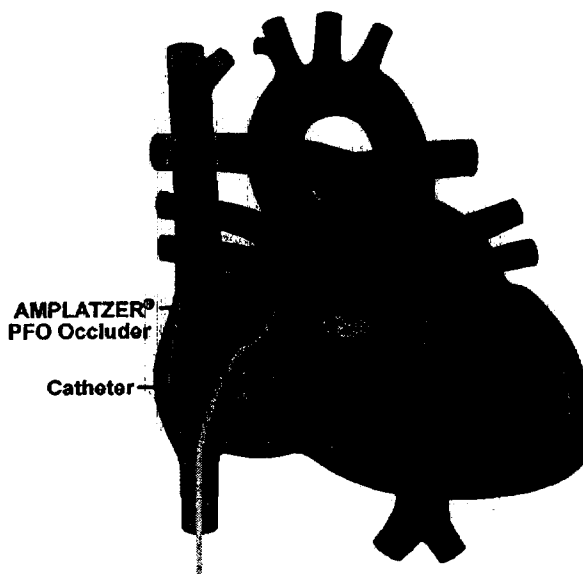


Figure 5
Diagram of the heart with the device in place

8. The *catheter* and *imaging probe* (if used) are removed and the procedure is completed.

The procedure generally takes 1-2 hours. The procedure is less invasive than open-heart surgery. Many patients have the procedure done in the morning and go home at the end of the day or the following morning.

WHAT TO EXPECT AFTER THE PROCEDURE

After recovery from anesthesia and bed rest, you should be able to sit up and walk about. If there are no complications, you may go home that day or stay overnight in the hospital.

Before you leave the hospital, a chest X-ray and/or *echocardiogram* will be performed to make sure the device is still positioned properly.

Because the procedure is less invasive than open-heart surgery, your recovery should be easier. You may have an adhesive bandage where the *catheter* was inserted. You also may have a sore throat if an *imaging probe* was used.

Before you leave the hospital, your doctor will give you guidelines for activities and medications. Your doctor should tell you when you can resume normal daily activities. Medications will be an important part of your treatment. Your doctor will prescribe drugs that you should take at home. The drugs should prevent blood clots from forming. Notify your doctor if your medications cause unpleasant reactions, but do not stop taking them unless instructed to do so. Your doctor may be able to prescribe new medications that better suit you.

You will be required to take medication every day for the next six months to help prevent blood clots (*antiplatelet/anticoagulation*) and will be required to take antibiotics for certain medical procedures to minimize the risk of infection of the device. The decision to continue taking medication beyond 6 months is at the discretion of your doctor.

It is important to keep all follow-up appointments that are scheduled for you. You will have to return to your doctor for periodic follow-up visits over the next year.

ALTERNATIVES TO THE DEVICE AND TREATMENT

- Surgery to close your PFO
- Continuing to take medication
- Treatment with a different HDE Approved Device
- No treatment

FREQUENTLY ASKED QUESTIONS

Will I experience pain from the procedure?

You may experience some discomfort in the groin area where the incision was made to insert the catheter. You may also experience a sore throat from the echocardiogram imaging probe. These symptoms should go away within a few days to a week.

Will I be able to feel the implant?

No, you will not be able to feel the implant.

What happens with an AMPLATZER PFO Occlusion device once it gets implanted?

The device will remain permanently implanted in your body. It will take a matter of 3-6 months before the device is completely covered by tissue. At that point, the device will become a part of the wall of your heart and will only be visible by X-Ray.

What activities should be avoided after my procedure? When can they resume?

All strenuous activity should be avoided for one month after the procedure. Even though you may feel ready to resume your normal activity, you should take it easy for at least one month.

What happens if I need an MRI (Magnetic Resonance Imaging)?

Your AMPLATZER PFO Occluder device is **MRI** compatible. If an MRI is needed, the MRI staff should be informed about the presence of your implant. You will receive an identification card that you should always carry with you and show to medical personnel.

If I travel, can I go through metal detectors without setting off an alarm?

Your Amplatzer PFO Occluder device should not set off metal detector alarms. The AMPLATZER PFO Occluder is not magnetic. Once again, your identification card should be shown to airport security if necessary.

Can I have this procedure if I am pregnant?

The risk of increased x-ray exposure must be weighed against the potential benefits of this technique. Your doctor will ensure that care will be taken to minimize the radiation exposure to the fetus and the mother.

What if I am a nursing mother?

It is unknown if the device affects breast milk. You should discuss this issue with your doctor.

QUESTIONS FOR YOUR PHYSICIAN

Use this page to write down any questions or concerns you would like to discuss with your doctor. Remember to follow your doctor's advice to ensure a smooth recovery.

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For additional information, please contact AGA Medical Corporation
1-888-546-4407 or access our web site at www.amplatzer.com